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UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

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Washington, D.C. 20231

ATTORNEY DOCKET NO. APPLICATION NO. **FILING DATE** FIRST NAMED INVENTOR

08/944.850

10/06/97

WALT

TU-97-01

MMC1/0412

EXAMINER

HANNAHER, C

ART UNIT

PAPER NUMBER

2878

D

DATE MAILED:

04/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| Office Action Summary | Application No. | Applicant(s) | Applicant(s) | |
|---|------------------------------------|--|--------------|--|
| | 08/944,850 | WALT ET AL. | | |
| | Examiner | Art Unit | | |
| | Constantine Hannaher | 2878 | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | |
| Period for Reply | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | | | |
| Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. | | | | |
| If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. | | | | |
| - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). | | | | |
| Status 1)⊠ Responsive to communication(s) filed on <u>14 February 2000</u> . | | | | |
| 2a) ☐ This action is FINAL . 2b) ☐ This action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | |
| Disposition of Claims | | | | |
| 4)⊠ Claim(s) <u>28-38</u> is/are pending in the application. | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | |
| 5) Claim(s) is/are allowed. | | | | |
| 6)⊠ Claim(s) <u>28-38</u> is/are rejected. | | | | |
| 7) Claim(s) is/are objected to. | | | | |
| 8) Claims are subject to restriction and/or election requirement. | | | | |
| Application Papers | | | | |
| 9) The specification is objected to by the Examiner. | | | | |
| 10) The drawing(s) filed on is/are objected to by the Examiner. | | | | |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved. | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | |
| Priority under 35 U.S.C. § 119 | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been: 1.☐ received. | | | | |
| 2. received in Application No. (Series Code / Serial Number) | | | | |
| 3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | |
| 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e). | | | | |
| Attachment(s) | | | | |
| 14) Notice of References Cited (PTO-892) 15) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 18) Notice of I | Summary (PTO-413) Paper I nformal Patent Application (I | | |
| 16) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 | <u>3,<i>15</i>,<i>16</i></u> . 19) | • | | |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the invention of Group II in Paper No. 17 is acknowledged.

Information Disclosure Statement

2. As set forth in MPEP § 609:

37 CFR 1.98(b) requires that each U.S. patent listed in an information disclosure statement be identified by patentee, patent number, and issue date. Each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application. Each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. The place of publication refers to the name of the journal, magazine, or other publication in which the information being submitted was published.

Note the articles to Drmanac *et al.* in the citation of January 6, 2000 and one or more of the other documents listed in the citation of December 2, 1999. The month of publication has been supplied where apparent.

3. The information disclosure statement filed December 2, 1999 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).
- 6. Claims 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al. (US005866331A).

With respect to independent claim 28, Singer et al. discloses a method for addressing the characteristic optical response signature (which in the disclosure of Singer et al. is fluorescence) of a sensor array having subpopulations of different sensor elements (probes which are different based at least on their spatial location) comprising the steps of measuring the optical response signature of at least two of the sensor elements of at least one of the subpopulations (col. 7, lines 1-2) and summing the optical response signatures (col. 7, lines 5-7). The description of the summation of "All pixels" in the disclosure of the method of Singer et al. represents at least two of the sensor elements of at least one of the subpopulations as recited since the scope of the claim includes the measurement and

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summation of the optical response signature of all the sensor elements of all the subpopulations. In the context of a method capable of detecting and locating a single target-bound probe, it would have been obvious to one of ordinary skill in the art that the method of Singer *et al.* improved the signal-to-noise ratio in the characteristic optical response signature.

With respect to dependent claim 29, the baseline of at least one optical response signature is adjusted in the method of Singer et al. (col. 7, lines 4-5).

With respect to dependent claim 30, the improvement in the signal-to-noise ratio in the method of Singer et al. is a choice within the ordinary skill in the art in view of the desired performance.

With respect to dependent claim 31, a reduction in the analyte detection limit in the method of Singer et al. is a choice within the ordinary skill in the art in view of the desired performance.

With respect to dependent claim 32, the sensor array in the method of Singer et al. comprises a population of beads dispersed on a substrate (col. 13, lines 58-60).

With respect to dependent claim 33, although the substrate in the method of Singer et al. is the microscope slide or cover slip, the provision of a fiber optic bundle would have been within the ordinary skill in the art in view of the flexibility afforded in positioning the sensor array.

With respect to dependent claim 34, the method of Singer et al. further comprises the step of locating each sensor element (abstract, line 6) in view of the imaging techniques and CCD camera.

With respect to dependent claim 35, the sensor elements in the method of Singer et al. comprise chemical functional groups (col. 10, lines 52-57).

With respect to dependent claim 36, the sensor elements in the method of Singer et al. comprise oligonucleotides (col. 4, lines 54-57).

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With respect to independent claim 37, Singer et al. discloses a method for addressing the characteristic optical response signature (which in the disclosure of Singer et al. is fluorescence) of a sensor array having subpopulations of sensor elements (probes which are different based at least on their spatial location) comprising the steps of measuring the optical response signature of at least two of the sensor elements of at least one of the subpopulations (col. 7, lines 1-2) and summing the optical response signatures (col. 7, lines 5-7). The description of the summation of "All pixels" in the disclosure of the method of Singer et al. represents at least two of the sensor elements of at least one of the subpopulations as recited since the scope of the claim includes the measurement and summation of the optical response signature of all the sensor elements of all the subpopulations. In the context of a method capable of detecting and locating a single target-bound probe, it would have been obvious to one of ordinary skill in the art that the method of Singer et al. amplified the characteristic optical response signature.

With respect to dependent claim 38, the baseline of at least one optical response signature is adjusted in the method of Singer et al. (col. 7, lines 4-5).

Response to Submission(s)

- 7. The amendment filed February 14, 2000 has been entered. The instruction to make amendment to page 40, line 5 has been applied to line 4 instead. The instructions to make amendments to page 41, lines 3-7 and 12-21 and pages 42-45 are defective and have not been entered.
- 8. The Examiner devoted some effort to determine the overlap between the lists included with the submissions of December 2, 1999 and February 14, 2000.
- 9. Applicant's arguments filed February 14, 2000 have been fully considered but they are not persuasive. The argument relies on importation of limitations from the specification regarding the

meaning of sensor array, subpopulation, different, and sensor element. The independent claims do not even require that the optical response signature be fluorescence. For at least the reasons explained above, Applicant is not entitled to a favorable determination of patentability in view of the arguments submitted February 14, 2000.

Conclusion

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Constantine Hannaher whose telephone number is (703) 308-4850. The examiner can normally be reached on Monday-Friday with flexible hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seungsook (Robyn) Ham can be reached on (703) 308-4090. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and Not Established for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

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Constantine Hannaher
Primary Examiner

ch April 10, 2000